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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,842	09/09/1999	SAMUEL P. SAWAN	SUR-008	1863

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 12/31/2001

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/392,842

Applicant(s)

SAWAN ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-57 and 72-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Amendment filed on October 10, 2001 has been entered. Claims 1-88 are pending. Claims 58-71 are under consideration. This application contains claims 1-57, 72-88 drawn to an invention nonelected without traverse as set forth in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites a "non-metallic composition comprising;" yet according to the claims 61-64, the polymeric moiety of the composition contains metallic elements. Thus, the composition as a whole encompasses metallic containing species of polycationic polymer which renders the instant compositions metal containing. Accordingly, the metes and bounds of the claims are not clear.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Applicant's arguments filed on October 10, 2001 have been fully considered but they are not persuasive for the reasons discussed below.

Claims 58-71 stand rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/18330 ('330).

Applicant argues that '330 does not teach application of non-metallic composition to skin. In reply Examiner states that the instant claim language comprise and do not exclude limitations of prior art. Examples 1, and 13-15 of '330 disclose non-metallic compositions solely made of a polycationic polymer or adducts thereof. Thus, '330 discloses non-metallic antibacterial compositions.

Moreover, broad interpretation of "administering to skin" includes any method of application to a skin. '330 discloses such methods of application. Specifically, example 9, page 31, line 15 of '330, explicitly recite that when the coating compositions of '330 are "worn by human volunteers for a 3 day period, no skin reaction was noted." In fact, the coating of example 10 kills micro-organisms with no toxic effects on mammalian cells (see page 31, line 18). Thus, '330 not only discloses non-metallic antimicrobial compositions but also teaches administration of such compositions to skin. Accordingly, '330 anticipates the instant claims for the reasons of record.

Claims 58-61 stand rejected under 35 U.S.C. 102(b) as being anticipated by Brown US Patent 4,683,181 (Brown).

Applicant argues that Brown does not teach application of a composition to skin. In reply Examiner states that the instant claim language comprise and do not exclude limitations of prior art. Applicant is reminded that during patent examination, the pending

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claims are "given the broadest reasonable interpretation consistent with the specification." MPEP 2111. In the instant case, Brown clearly teaches administration of a composition comprising PHMB as a 20% aqueous solution to skin (see example VI, col 8, lines 55-68, col 9, lines 1-15). Thus, Brown anticipates the instant claims.

Claims 61-64 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sawan et al WO 95/17152 ('152).

Applicant argues that unlike the instant compositions, the '152 is directed to metallic containing compositions. This argument is not persuasive as the pending claims are viewed given the broadest reasonable interpretation. The instant compositions clearly encompass metal-containing species (see instant claims 61-64). Thus, '152 anticipates the instant claims for the reasons of record.

Claims 61-64 stand rejected under 35 U.S.C. 102(e) as being anticipated by Sawan et al US Patent 5,817,325 (Sawan).

Applicant argues that unlike the instant compositions, Sawan is directed to metal containing compositions. For the same reasons as above, this argument is not found persuasive, because the instant compositions encompass metal containing formulations (see instant claims 61-64). Thus, Sawan anticipates the instant claims for the reasons of record.

^{61-64 ss}
Claims ~~58-71~~ stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,180,584; US Patent 6,030,632; US Patent 5,869,072; US patent 5,817,325 for the reasons of record.

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Applicant argues that the instant compositions are not directed to metallic containing compositions. However, the recitations of the instant claims are clearly directed to the compositions encompassing metal containing compositions (see instant claims 61-64), thus, claims stand rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss

December 28, 2001



DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600